NHGRI IRB: Checklist for New Protocols

(Include 1 copy with submission)

Principal Investigator: _____

Protocol Title: _____

Note: all new Investigators must complete Computer Based Training at http://www.nihtraining.com/ohsrsite/cbt/cbt.html.

I. NEW PROTOCOL FOR IRB REVIEW (*original + 25 stapled copies*)

- ❑ Form 1195 signed by PI, Accountable Investigator, SRC Chair, and Branch Chief.
- ❑ Cover memo to IRB including PI's responses to SRC review.
- ❑ SRC review.
- ❑ Table of contents listing protocol and any appendices, recruitment materials, and consent forms.
- ❑ NHGRI Human Subjects Research Protocol including Target/Planned Enrollment Table.
- ❑ Appendices including questionnaires, educational materials, investigator's brochure, etc.
- ❑ Participant recruitment materials.
- ❑ Consent form(s).

II. RESPONSES TO STIPULATIONS FOR CONDITIONALLY APPROVED PROTOCOLS

- ***originial + 25 stapled copies if full IRB review required***
- ***original + 6 stapled copies if IRB Subcommittee review required***
- ***original + 3 stapled copies if NHGRI IRB Chair review required***

- ❑ Cover memo responding point-by-point to stipulations.
- ❑ Revised pages of protocol and consent, with the additions and ~~deletions~~, so noted.
- ❑ Copy of IRB Meeting Minute Stipulations.
- ❑ Clean copies of entire revised protocol and consent.
- ❑ Diskette or e-mail containing clean, final copy of consent form.

Materials for full IRB review must be submitted to Peggy McKoy Bldg 49, Room 4A14 by Noon on the due date, or they may be reviewed at a later meeting. (See NHGRI IRB Calendar).

For questions regarding the checklist or submissions, please contact:

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